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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,672	10/17/2005	Yoshiki Kawabe	KAWABEI	1850
1444 7590 10/09/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER STOICA, ELLY GERALD	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 10/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/553,672

Applicant(s)

KAWABE ET AL.

Examiner

Elly-Gerald Stoica

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7,10 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,7,10 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>02/20/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of 1,4, 7 and 16 in the reply filed on 08/13/2007 is acknowledged. The traversal is on the grounds that, in view of the amended claims submitted, the claims do not lack the same special technical feature. This argument is found persuasive and the amended claims pending, 1, 4, 7, 10 and 14-16 are subject to the examination together. Claims 2, 3, 5, 6, 8, 9 and 11-13 were cancelled by Applicant.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 4, 7, 10 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what method step is indicated by part b) of the claims: what is it that consists of the active step of a person of ordinary skill in the art needs to perform in order to achieve what is mentioned in the preamble. Also unclear is the recipient of the administered ingredients. Also, neither claim conclude with what the preamble stated. Therefore, the meets and bounds of the claims could not be determined.

The claims are also indefinite because there is no clear and accepted definition of stem-cell recruiting factors. The specification mention stem cell recruiting factors by recitation only. Therefore the meets and bounds of the claims could not be determined.

Claim 15 is also indefinite because it depends on a cancelled claim (claim 11).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 4, 7 and 16 rejected under 35 U.S.C. 102(b) as being anticipated by Lechner et al. (am. J. Physiol. Endocrinol. Metab. 284, E259-E266, 2003, - cited by the Applicant).

Lechner et al. teach two approaches to treating diabetes and preventing/regenerating insulin-producing cells (beta cells in Langerhans' islets). One approach is to prepare islets from stem cells differentiated in vivo and then administered to the patient. A second approach is to administer multipotential stem cells systematically to the patient and co-administration of stem cell stimulators/differentiators such as GLP-1, thus establishing a permanent self-renewing population of stem/progenitor cells to provide a continued source of functional beta cells (p E264, left col. second full paragraph). Since there is no consensus about the definition of stem cell-recruiting factors and the specification mentions that G-CSF (which is one of the examples of the stem cell-recruiting factors cited) is a stimulator /differentiation agent, GLP-1 reads on the scope of the claims. By practicing the teachings of Lechner et al., a

person of ordinary skill in the art would have practiced the claims of the instant Application. Therefore, Lechner et al. anticipates the claims 1, 4, 7 and 16 of the instant Application.

6. Claims 1, 4, 7, 10 and 14-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Hussain M. (WO/2004/030628, filed on 10/02/2003 with a priority date of 10/02/2002-60/415,091).

Hussain teaches a subpopulation of bone marrow cells which are capable of differentiating into insulin-producing pancreatic islet cells and to a method for treating a diabetic condition by administering adult bone marrow derived stem cells which can differentiate and then function as pancreatic islet cells ([0002]). Also taught is a method for stimulating the mobilization of cells from bone marrow and the differentiation of bone marrow derived cells into pancreatic islet cells, by treating such bone marrow-derived cells with an effective stimulating amount of granulocyte colony stimulating factor (G-CSF) and/or granulocyte-macrophage colony stimulating factor (GM-CSF). The method is performed in conjunction with a method for treating a diabetic condition in a mammal, by administering a therapeutically effective amount of bone marrow or an effective subpopulation thereof in combination with purified recombinant G-CSF or GM-CSF in an amount effective to stimulate the mobilization and differentiation of some of the bone marrow cells into pancreatic islet cells ([0010]). The cells used in the method are adult bone marrow cells that have pluripotent differentiation capacity. Such cells, when transplanted, have the potential to restore function of certain endocrine cells to a patient who has lost such production due to disease such as diabetes mellitus. Thus bone

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marrow derived cells populate pancreatic islets of Langerhans. When purified from islets, said cells express insulin, the glucose transporter 2 (GLUT2), and transcription factors typically found in pancreatic beta cells ([0020]). The teachings of Hussain established that bone marrow harbors cells that can differentiate into functionally competent pancreatic endocrine beta cells and thus represent a source for cell-based treatment for diabetes mellitus ([0021] and claims 14-17). The performing of the method for treating and/or preventing a diabetic condition in a mammal in need thereof by administering to the mammal a therapeutically effective amount of autologous or non-autologous bone marrow or an effective subpopulation thereof, wherein the autologous or non-autologous bone marrow, or effective subpopulation thereof, is administered with purified recombinant G-CSF and/or GM-CSF in an amount effective to stimulate the mobilization and differentiation of some of the bone marrow cells into pancreatic islet cells ([0024]) would necessarily prevent the beta -cell disruption by the inherent properties of the G-CSF administered. Therefore, the teachings of Hussain anticipate the claims 1, 4, 7, 10 and 14-16 of the instant Application.

Conclusion

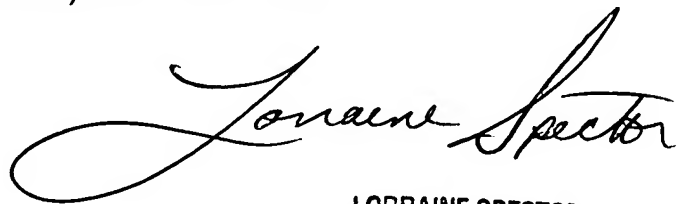
7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in cursive script, reading "Lorraine Spector". The signature is fluid and elegant, with a large loop at the end of the last name.

**LORRAINE SPECTOR
PRIMARY EXAMINER**